7/28/98 **FACT SHEET**

FINAL AIR TOXICS RULE FOR PHARMACEUTICAL PRODUCTION

TODAY'S ACTION...

- Under authority of the Clean Air Act Amendments of 1990, the Environmental Protection Agency (EPA) is finalizing a regulation to reduce emissions of air toxics from the manufacture of pharmaceutical products, such as prescription and over-the-counter drugs and other medicines. Air toxics are those pollutants that are known or suspected of causing cancer or other serious health effects.

- Today's action demonstrates EPA's commitment to making pollution prevention an integral part of regulatory actions whenever possible. EPA's final rule provides facilities with an alternative, pollution prevention-based standard as an option for complying with the rule's requirements. The pollution prevention-based option would require a reduction in the consumption of solvents (which are also toxic air pollutants) during the manufacturing process.

- This notice presents an interpretation of current regulations (40 C.F.R. part 70) to allow an experimental approach for title V operating permits which provide for operational flexibility without frequent permit revision.

- EPA developed today's rule in close partnership with major stakeholders, including industry representatives and state and local agencies.

WHAT ARE THE HEALTH AND ENVIRONMENTAL BENEFITS?

- EPA's final rule would reduce emissions of a number of air toxics, including methanol, methylene chloride, toluene, and hydrogen chloride. Methylene chloride is considered a probable human carcinogen, and the other pollutants can cause a variety of health effects in humans.

- EPA's final rule would reduce emissions of air toxics by approximately 24,000 tons annually, representing a 65 percent reduction from current levels. Many facilities subject to the rule have already installed stringent air pollution controls.

BACKGROUND

- Under the Clean Air Act Amendments of 1990, EPA is required to regulate emissions of 188 listed toxic air pollutants (Note that this list originally contained 189 pollutants, but EPA has subsequently removed the chemical caprolactum from the list.). On July 16, 1992, EPA published a list of source categories that emit one or more of these air toxics. For listed categories of "major" sources (those that emit 10 tons/year or more of a listed pollutant or 25 tons/year or more of a combination of pollutants), the Clean Air Act

requires EPA to develop standards that require the application of stringent air pollution controls, known as maximum achievable control technology (MACT).

- EPA's published list of industry groups (known as "source categories") to be regulated includes major sources that manufacture pharmaceutical products.

WHAT DOES EPA'S FINAL RULE REQUIRE?

- The pharmaceutical manufacturing process consists mainly of chemical production operations used to produce drugs and medication. These operations include chemical synthesis (deriving a drug's active ingredient) and chemical formulation (producing a drug in its final form). EPA's final rule would set an emissions limit or control efficiency requirements for the following emissions points at affected sources or facilities: storage tanks, process vents, equipment leaks, wastewater collection and treatment systems, and cooling towers.

- The monitoring, recordkeeping and reporting requirements are outlined in the rule.

HOW DOES EPA'S FINAL RULE PROVIDE FLEXIBILITY TO INDUSTRY?

- Today's action would provide industry with the option of complying with the regulation through an alternative, pollution prevention-based standard. The alternative standard would require significant reductions in the amounts of toxic air pollutants used during the manufacturing process. It would allow facilities to focus on improving processes by reducing solvent loss and incorporating solvent recovery and reuse techniques.

- EPA's final rule also contains a market-based provision, "emissions averaging," that would allow facilities flexibility to choose certain emissions points to control in order to achieve the required emissions reductions in the most cost-effective manner possible. The rule would allow facilities to use emissions averaging among process vents and storage tanks. In some situations, facilities may find it more cost-effective to overcontrol these emissions points and undercontrol others, so that the overall result would be greater emissions reductions at lesser control costs. The rule spells out how facilities would be able to use emissions averaging.

- The final rule contains an alternative standard that limits outlet emissions to a specified level (i.e. 20 parts per million by volume). This alternative standard simplifies monitoring and recordkeeping for control devices servicing more than one process and provides a control strategy for dilute emission streams.

- The final rule also allows facilities to choose between controlling the sum of all process vent emissions from a process either by reducing the uncontrolled emissions by 93 percent or by limiting the emissions from the process to 2,000 pounds per year.

WHO WOULD BE AFFECTED BY EPA'S FINAL RULE?

- There are about 100 pharmaceutical manufacturing facilities nationwide that would be affected by this rulemaking.

HOW MUCH WOULD THE FINAL RULE COST?

- The capital cost of the final rule for all affected facilities is estimated to be about $183 million (1995 dollars).

- The total annual cost of the rule is estimated to be about $73 million (1995 dollars) for existing and new facilities.

- EPA expects that the actual compliance cost impacts of the standard would be less than projected because of the potential to use common control devices; upgrade existing control devices; use other less expensive control technologies; implement pollution prevention technologies; and employ emissions averaging.

- The price of pharmaceutical products for consumers is projected to increase by about one percent.

FOR FURTHER INFORMATION...

- Interested parties can download the rule from EPA's web site on the Internet under "recent actions" at the following address: (http://www.epa.gov/ttn/oarpg). For further information about the proposal, contact Randy McDonald of EPA's Office of Air Quality Planning and Standards at (919) 541-5402.

- EPA's Office of Air and Radiation's homepage on the internet contains a wide range of information on the air toxics program, as well as many other air pollution programs and issues. The Office of Air and Radiation's home page address is: http://www.epa.gov/oar.